

REMARKS

In the Office Action dated February 24, 2004, claims 8-14 were examined with the result that all claims were rejected. In response, applicant submits the following comments. In view of these comments, reconsideration of this application is requested.

In the Office Action, the Examiner initially rejected claims 8-14 under 35 USC §112, first paragraph, as containing new matter. The Examiner alleges that the specification as originally filed does not provide support for “a method of reducing the amount of phosphorus and cow manure, comprising replacing a 1 α -hydroxylated vitamin D compound for some or all of the inorganic phosphorus in the diet of a dairy cow” and “feeding said diet to said dairy cow.” The Examiner alleges that the specification as originally filed merely discloses that the present invention is directed toward a method of maintaining milk production in a dairy cow while at the same time “minimizing” the need for supplemental inorganic P and increasing utilization of phytate P in the cow’s diet”. The Examiner then cites page 5 of the specification in support of the Examiner’s position.

First, applicant would like to point out that claim 8 is in fact directed toward a method of maintaining milk production in a dairy cow, and is not directed toward a method of reducing the amount of phosphorus in cow manure, as stated by the Examiner. Applicant believes the Examiner mistakenly referred to the previously amended claim 8 which was submitted with the prior Amendment dated July 23, 2003, and which the Examiner considered non-responsive in the Office Action dated October 21, 2003. This amendment to claim 8 was not entered by the Examiner, and accordingly applicant filed a Supplemental Amendment dated November 21, 2003 wherein the claim was once again directed toward a method of maintaining milk production in a dairy cow. Support for such a claim can clearly be found in the specification as originally filed. For example, original claim 1 was directed toward a method of maintaining milk production in a dairy

cow, and in fact the "object" referred to by the Examiner on page 5, lines 7-10 also supports this portion of the preamble to claim 8. Thus, applicant believes this portion of claim 8 is clearly supported by the original specification as filed and is not new matter.

It appears that the Examiner is actually directing this objection to the fact that claim 8 calls for "replacing" some or all inorganic phosphorus in a diet for a dairy cow with a 1α -hydroxylated vitamin D compound. Applicant believes the crux of the Examiner's objection is to the word "replacing" as well as the phrase "some or all" inorganic phosphorus contained in the above referred to step of the method since these portions of the rejection were emphasized by being underlined in the rejection. First, in regard to the term "replacing" the inorganic phosphorus with a 1α -hydroxylated vitamin D compound, applicant refers the Examiner to page 6, lines 12-14. Applicant states that "by replacing some or all of the trace minerals (e.g. Zn, Mn and Fe) as well as inorganic P normally supplied in the diet as a supplement to dairy cattle, the remaining diet would contain more usable energy." The term "replacing" utilized by applicant is clearly referring to the substitution of a 1α -hydroxylated vitamin D compound for some or all of the inorganic phosphorus in the diet of a cow. The entire "Summary of the Invention" section of the application is describing the incorporation of 1α -hydroxylated vitamin D compounds into the diet of a dairy cow in order to accomplish various beneficial results, such as the reduction of the need for inorganic phosphorus supplements. This is clearly demonstrated by the sentence found at page 5, lines 14-15 wherein applicant states: "In accordance with the above objects of the invention, a feed supplement for a dairy cow includes an effective amount of 1α -hydroxylated vitamin D compound." Thus, the reference to "replacing" found at page 6, lines 12-14 is clearly referring to replacing minerals such as inorganic P with an effective amount of a 1α -hydroxylated vitamin D compound.

The term "some or all" is also found at the above referenced location at page 6, lines 12-14. Again, this clearly supports the use of the phrase "some or all" in claim 8. In addition, applicant refers the Examiner to page 5, lines 2-4 wherein applicant specifically states that it is an object of the present invention to provide a feed supplement for a dairy cow that "eliminates or at least substantially reduces the need for supplemental inorganic P in the cow's diet." Clearly applicant is stating that all of inorganic P in the cow's diet may be eliminated (i.e. by the term "eliminates"), and the applicant also is stating that "some" of the inorganic P in the cow's diet may be replaced (i.e. by the phrase "at least substantially reduces"). Thus, applicant believes that it has not introduced any new matter to claim 8, and respectfully requests the Examiner withdraw the new matter rejection.

In the Office Action, the Examiner also objects to claim 11 as containing new matter. Claim 11 states that the feed contains "0% by weight of an inorganic phosphorus supplement." The Examiner alleges that a feed containing no inorganic phosphorus supplement is not supported by the original specification as filed. Applicant, however, respectfully disagrees. For example, applicant refers the Examiner to the first object of the invention set forth on page 5, lines 2-4. This object refers to a feed supplement that "eliminates" or at least substantially reduces the need for supplemental or inorganic P in the cow's diet. The term "eliminates" clearly implies that no supplemental inorganic P can be present in the cow's diet. Next, applicant refers the Examiner to page 5, lines 19-22 wherein applicant states the following:

"By incorporating a 1α -hydroxylated vitamin D compound in the diet of a dairy cow, the feed can be formulated with only about 0.3% by weight or less of inorganic P supplements, and preferably with no inorganic P supplementation." (emphasis added)

This portion of the description clearly states that the feed fed to a dairy cow preferably contains "no inorganic P supplementation". This clearly implies that there is 0% by weight of inorganic phosphorus supplement. Next, applicant refers the Examiner to page 6, lines 12-14. As previously noted, this portion of the description states that "some or all" of inorganic P can be replaced by a 1 α -hydroxylated vitamin D compound. The term "some or all" clearly implies that all or 100% of the inorganic P can be replaced, which in turn means that the feed will contain 0% by weight of an inorganic phosphorus supplement. Next, applicant refers the Examiner to page 9, lines 27-29 wherein applicant states:

"The amount of an inorganic phosphorus supplement (18.5%P) that is typically incorporated with the feed may be reduced to 0.3% or less by weight or may be entirely eliminated from the cow's diet." (emphasis added)

Again, this statement clearly tells one skilled in the art that one can entirely eliminate the inorganic phosphorus from a cow's diet. This inherently means that the feed contains 0% by weight of an inorganic phosphorus supplement. Finally, applicant refers the Examiner to original claim 4 with the application as filed. Original claim 4 states that the feed contains "0% by weight of an inorganic phosphorus supplement." Thus, claim 4, being part of the original description, clearly supports claim 11 as herein presented which states that the feed contains 0% by weight of an inorganic phosphorus supplement. Accordingly, applicant believes the Examiner should withdraw the new matter rejection of claim 11.

In the Office Action, the Examiner rejected claims 8-14 under 35 USC §112, second paragraph, as being indefinite. The Examiner alleges that recitation of the word "some" in claim 8 renders claim 8 indefinite because the term "some" is a relative term.

The Examiner alleges that one skilled in the art could not determine what the word "some" would mean in claim 8. Applicant, however, respectfully disagrees for the following reasons.

The term "some" is defined in Webster's New Collegiate Dictionary as being an unspecified or indeterminate quantity, portion, or number as distinguished from the rest of an amount. Although at first glance the term "some" appears relative and therefore indefinite, applicant believes that under the present circumstances the term "some" is not indefinite. If one knows the total amount, the word "some" clearly implies that a part or portion of that total amount is being referred to. Thus, if a diet contains 0.9% P, the term "some" clearly implies that an amount between 0% and 0.9% is being referred to. Thus, if one skilled in the art were told to replace "some" of the 0.9% P with a 1 α -hydroxylated vitamin D compound, it is clear to that person that an amount between 0% and 0.9% needs to be replaced. It seems to applicant that under the present circumstances, the term "some" is not indefinite. Although applicant might concede that under other circumstances the term "some" would be indefinite, applicant does not believe this is so under the circumstances presented by claim 8 herein. Thus, applicant believes the Examiner should withdraw the indefiniteness rejection of claim 8 based on the word "some" as being a relative term.

In the Office Action, claims 8-10 and 12-14 were rejected under 35 USC §102(b) as being anticipated by DeLuca et al WO 96/24258. It is the Examiner's position that this reference anticipates these claims. Applicant, however, respectfully disagrees for the following reasons.

WO 96/24258 is directed solely to the increased utilization of phytate phosphorus. Phytate phosphorus is an organic source for phosphorus as phosphorus and phytate exists as a complex of phytic acid and is schematically illustrated by the formula found on pages 1 and 2 of the reference cited by the Examiner. Although this reference may also discuss reduction of supplemental inorganic phosphorus due to the use of vitamin D compounds, it does so only in the context that vitamin D compounds increase utilization of

phosphorus from the phytate complex. The reference never teaches or suggests that vitamin D compounds increase utilization of phosphorus from inorganic sources. For example, at page 5, lines 27-29 the reference states:

"The net effect would be an increased utilization of P
(also Zn, Fe, Mn and Ca) from the phytate complex."

This is further demonstrated by original claim 11 wherein it states that an animal feed composition contains an effective amount of an 1α -hydroxylated vitamin D compound "for utilizing phosphorus from phytate complexes in said diet." The same is true of claim 18 relating to a method of minimizing dietary requirements of phosphorus in animals. Again, claim 18 refers only to utilizing phosphorus from phytate complexes. This is also true of original claim 27 which claims a method of reducing the polluting effects of phosphorus on the environment wherein once again the claim calls for using phosphorus from phytate complexes. Finally, original claim 36 is directed to a method of degrading phytate complexes in animal feed. Thus, the entire disclosure and description set forth in WO 96/24258 is directed toward utilization of phosphorus in phytate complexes, and there is nothing in this reference that teaches or suggests that 1α -hydroxylated vitamin D compounds could be used to increase utilization of phosphorus from inorganic sources. Thus, applicant believes the Examiner should withdraw the objection of claims 8-10 and 12-14 based on this reference.

In the Office Action, claims 1 and 12-13 were rejected under 35 USC §102(b) as being anticipated by DeLuca et al U.S. 4,338,312. The Examiner states that the '312 reference teaches that 1α -hydroxylated vitamin D compounds are useful in a method of treating dairy cattle for parturient paresis, and thus this teaching inherently teaches a method of maintaining milk production in the dairy cow. Thus, the Examiner believes the '312 reference anticipates the claimed invention. Applicant respectfully disagrees for the following reasons.

U.S. Patent 4,338,312 cited by the Examiner relates to treatment of milk fever disease. There is no suggestion in the '312 patent of substituting a 1α -hydroxylated vitamin D compound for some or all of the inorganic phosphorus in the cow's diet and then feeding that diet to the cow on a daily basis to maintain milk production at normal levels despite the low P content in the cow's diet. The entire disclosure of the '312 patent relates to a method for treating dairy cattle for parturient paresis. The disclosure of the '312 patent is thus limited to treatments for a disease of dairy cows. It is clear that the '312 reference does not teach, suggest or even mention the substitution of 1α -hydroxylated vitamin D compounds for inorganic phosphorus in the cow's diet.

The Examiner should note that columns 1 and 2 of the '312 reference provides a partial summary of current treatments for milk fever, and in each instance, the administration of the vitamin D compound is accomplished by injection shortly before parturition, i.e. typically 3-7 days before calving. The passage at column 2, lines 27-29 states:

"If the vitamin D dosage is given too far in advance the incidence of milk fever disease is actually increased by the treatment."

The only conclusion that can be made from this statement is that a skilled person would readily recognize that giving a vitamin D compound to a dairy cow too far in advance of parturition would be ineffective and might be dangerous. The skilled person would infer that administering a vitamin D compound in the daily diet of a dairy cow would, in fact, increase the incidence of the disease, which is clearly an undesirable outcome. Thus, the '312 reference clearly teaches away from adding vitamin D compounds in the daily diet of a cow. Further, and more importantly, the '312 reference never teaches, suggests or infers in any way that the 1α -hydroxylated vitamin D compounds could be substituted for some or all of the inorganic phosphorus in the diet of a cow.

It is also clear from the '312 reference that the description therein is directed to the administration of the vitamin D compound only at a time closely adjacent to parturition or calving, and only for a short period of time, preferably every five days, but not daily. Nowhere does the '312 reference teach or suggest that a vitamin D compound could be substituted for some or all of the inorganic phosphorus in the diet of the cow.

Accordingly, applicant requests the Examiner withdraw the rejection based on the '312 reference.

In the Office Action, claims 1 and 12-13 were also rejected under 35 USC §102(b) as being anticipated by DeLuca et al U.S. 4,110,446. Again, the Examiner states that the '446 reference teaches a method of treating milk fever in dairy cattle and thus this method inherently teaches a method of maintaining milk production in a dairy cow. Applicant, however, respectfully disagrees for the following reasons.

First, applicant would like to reiterate that the same arguments referred to above with respect to the '312 reference can be made with respect to the '446 reference cited by the Examiner. Nowhere does the '446 reference teach or suggest that 1α -hydroxylated vitamin D compounds could be substituted for an inorganic phosphorus diet in a cow.

More specifically, at column 1, lines 55-59 of the above '446 reference it is taught that prior methods of treating milk fever include feeding a low calcium diet or feeding a high phosphate diet, but the Examiner will note that there is no description that such diets might be accompanied by incorporating 1α -hydroxylated vitamin D compounds therewith. In fact, at column 2, lines 1-16 of the '446 reference it is stated that treatment with massive doses of vitamin D compounds result in potentially higher risk of vitamin D toxicity. Thus, prior art methods actually teach away from incorporating vitamin D compounds into the daily diet of a dairy cow.

The '446 patent states that the invention taught therein relates to administering 1α , 25-dihydroxyvitamin D₃, and the passage at column 2, lines 37-42 states as follows:

"In general dosages of 1,25-DHCC in the range from about 200-400 μ g are effective in preventing milk fever when administered from about 24-74 hours before calving occurs. If more than 5 days elapses from the time of administering the first dose and calving has not occurred additional doses are given."

Thus, the '446 reference clearly teaches that the vitamin D compound is to be administered close to the time of parturition and not in the diet of the cow. Finally, it should be noted from the data in Tables 2 and 3 of the '446 reference that the longest period between the time of injection of the vitamin D compound and parturition was 12 days. One skilled in the art would clearly not consider giving an injection 12 days, then 7 days, and finally 2 days before parturition part of the daily diet of a dairy cow. In addition, since the injections are given during the time of parturition, it is the cow's "dry period" and thus one skilled in the art would clearly not equate injecting a cow during its dry period with a method of maintaining milk production in a dairy cow since a cow does not produce milk during its dry period.

For all the reasons noted above, applicant requests the Examiner withdraw the rejection based on the '446 reference.

In the Office Action, claims 9-11 were rejected under 35 USC §103(a) as being obvious over DeLuca et al '312 and DeLuca et al '446. The Examiner indicates that it would be obvious to optimize the effective amounts of vitamin D compounds to be administered. In response, and although applicant might agree that under some

circumstances it would be obvious to merely optimize dosages, applicant notes that there must be some motivation set forth in the references that would suggest to one skilled in the art to make the claimed combination. Applicant believes there is no such suggestion in the references cited by the Examiner. As discussed above, both the '312 and '446 references relate to a method for treating dairy cattle for milk fever disease. Both the '312 and '446 references teach that 1α -hydroxylated vitamin D compound is to be administered only during a very short period of time just prior to parturition and there is no suggestion to feed vitamin D compounds as part of a daily diet for a dairy cow.

As discussed in the introduction of the present patent application, much of the phosphorus in plant foods and feeds passes through the GI tract of the animal and is excreted in the animal's feces. In animal husbandry, this is accounted for in diet formulations by providing an inorganic phosphorus source in a feed supplement which is added to the normal diet to meet the animal's minimal phosphorus requirements. Since supplemental inorganic phosphorus is a relatively expensive ingredient in a dairy cow's diet, its reduction and/or elimination is desirable from a cost standpoint. However, in dairy cows, such a reduction of inorganic phosphorus cannot be made at the expense of milk yields. In the past, a skilled person would not have substituted a vitamin D compound for the phosphorus in a cow's diet because by doing so, one would not expect to meet the minimum phosphorus requirements of the animal which in turn would result in decreased milk production. Thus, new claim 8 clearly goes against the common teaching in the prior art.

The data in the present patent application demonstrates unexpected results over the prior art. A skilled person would not feed a diet to an animal which would not meet that animal's minimum phosphorus requirements. Otherwise, the diet would be assumed to be insufficient to provide adequate nutrition for the animal. Therefore, there is no motivation for a skilled person to substitute a 1α -hydroxylated vitamin D compound for

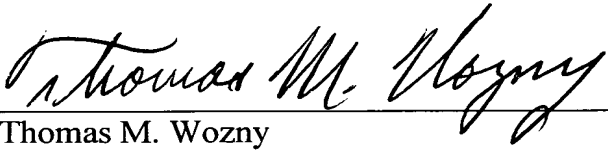
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some or all of the inorganic phosphorus in the diet of a cow. However, the data in the application as filed clearly show that, according to the present invention, although the diet contains low levels of phosphorus, milk production is maintained. To a skilled person, this is an unexpected result since it was normally assumed in the past that one needed to feed supplemental inorganic phosphorus to a cow to maintain its milk production. The substitution of a vitamin D compound for some or all of the inorganic phosphorus, and the subsequent maintenance of milk production, is an entirely unexpected result which would not have been predicted by a skilled person in light of the available prior art.

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

By 
Thomas M. Wozny
Reg. No. 28,922
(414) 271-7590

Andrus, Sceales, Starke & Sawall, LLP
100 East Wisconsin Avenue, Suite 1100
Milwaukee, Wisconsin 53202